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MARTIN MARIETTA CORPORATION

DENVER DIVISION

PLANETARY PROGRAMS

NEW CONCEPTS ON STERILIZATION I

ALTERNATIVES TO REDUCE THE PROBLEMS FROM TERMINAL HEAT STERILIZATION

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New Concepts on Sterilization - I

Alternatives to Reduce the Problems from Terminal Heat Sterilization

by

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ABSTRACT

Terminal heat sterilization is required for all unmanned planetary entry vehicles. This environmental treatment introduces high program risks from (1) hardware failures detected after the exposure, (2) heat sensitive items, and (3) the potential schedule effects causing inability to launch during the limited opportunity. This report analyzes alternatives to remedy this condition in the general categories of: (1) Added resources with the present constraints; (2) Modified recycle requirements; (3) Alternates to reduce the effect on launch site operations; and (4) Approaches to eliminate the terminal heat sterilization requirement. Of the alternates investigated, the Model Assembly Sterilizer (MAST) in combination with sterile insertion portends significant reduction in program risk. As concurrent fallout, the merits of a non-insulated packaging concept are identified; a planetary quarantine study and requirements for Venus cited and the need for a NASA approved surface sterilant is established.

PREFACE

This report is the first of a series of sterilization monographs devoted to the development of new ideas. Future reports will consider improvements and new concepts on such related sterilization activities as biological assays, sterile insertion, planetary quarantine, techniques for terminal heat sterilization, surface sterilants, sterilization/reliability/cost/schedule relationships etc. Conclusions and recommendations from these studies are intended to provide a baseline for Martin-Marietta management and technical decisions on TOS/RA funding and priority, interplanetary mission design and system approaches and suggestion for technically valuable NASA funded R & D contracts.

Comments on this report are solicited as well as suggestions for areas warranting detailed evaluation.

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I INTRODUCTION

By International Agreement, unmanned interplanetary probes landing on planets of the solar system will be sterilized to avoid contamination of the planet. In conformance to this agreement, NASA has established criteria for sterilization. The present NASA requirements entail terminal heat sterilization under biological kill conditions equivalent to 125°C for 24.5 hours. For reduction of biological contamination on surfaces, treatment with 12% ethylene oxide in a diluent of 88% Freon-12 under 30-50% RH is specified. After terminal sterilization, opening of the sterilization canister to effect repairs requires repetition of the terminal heat sterilization cycle. Under the present qualification conditions, one recycle after terminal heat sterilization is permissible.

From the standpoint of sterilized interplanetary missions, such as Voyager, Mars probe, Venus probe, etc., these present requirements introduce high risk in the program. These risks can be summarized as follows:

1. Failure After Terminal Sterilization: Data from previous missions indicates high failure occurrence at the launch site with non-sterilized missions.[1] This condition will be further compounded by the terminal heat sterilization as exemplified by the failures in the early Ranger series. Although an extensive NASA industry program has been underway to establish sterilizable

hardware, it would be unduly optimistic to assume that no failures will occur in the terminal sterilization, system checkout, handling and mating. After remedying such failures, the flight article must be recycled through terminal heat sterilization, system test, etc. This repetitive cycle introduces another opportunity for failure(s). Under present constraints, such failure(s) cannot be corrected without rendering the hardware unacceptable for the mission, i.e., only one cycle is permissible.

2. Heat Sensitive Items: At the present time a number of hardware items are not compatible with the terminal heat sterilization conditions. These include batteries, tape recorders, etc. In addition, the general area of scientific payloads have questionable compatibility. This area includes the problem of using dry heat to sterilize life detection experiments containing media in water.

3. Launch Period Constraints: Interplanetary missions have a limited launch period. Inability to launch will result in delays measured in years. In addition to the technical aspects, inability to launch would have far reaching political ramifications. Time for recycle coupled with the potential unavailability of flight articles caused by failure after recycle introduces a high risk of inability to launch in the prescribed time period.

In view of the serious nature of the present constraints, this study has been conducted to investigate alternatives which

could potentially alleviate these risks. These alternatives have been considered in a logical vein using the following groupings:

1. Present Requirements Apply; Expanded Program Scope: This alternative is based on living with the present conditions but adding to the program to reduce the risk. Under this classification, two categories are considered in this study comprising:

a) Increase the number of sterilization cycles during qualification to provide more recycle capability at the Cape; and

b) Increase the number of spacecraft spares to improve the probability of obtaining sterilized functional units.

2. Present Requirements Apply with Modified Recycle Requirements: This alternative accepts the initial terminal heat sterilization, but investigates alternates to repetition of the full terminal heat sterilization after repair. Three approaches are evaluated:

a) Lower heat sterilization requirements;

b) Ethylene oxide treatment;

c) Sterile replacement techniques*.

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* This area warrants more detailed analysis than provided in this report. This depth will be provided in a separate study.

3. Reduce Severity of Terminal Heat Sterilization at the Launch Site: This alternative approaches the problem from the standpoint of lowering the probability of failure under terminal heat sterilization. Three aspects are considered:

a) Conduct terminal heat sterilization at the factory;

b) Use the biological kill characteristics of the terminal heat sterilization treatment to reduce the total exposure time; and

c) Use sterile insulated assemblies to minimize failure occurrence of hardware inside the assembly.

4. Eliminate Terminal Heat Sterilization: This alternative considers solution of the problems by the radical approach of eliminating terminal heat sterilization. Three aspects are evaluated comprising:

a) Sterile assembly;

b) Sterile non-insulated biologically secure assemblies with gaseous sterilization; and

c) Partial sterilization using probability theory to conform to the basic international agreement of probability risk 1×10^{-3}.

II PRESENT REQUIREMENTS APPLY; EXPANDED PROGRAM SCOPE

A. Higher System/Subsystem Qualification Requirements

Concept: Under present NASA policy, qualification at the part, material and assembly level requires exposure to six sterilization and decontamination cycles. At the subsystem and system level, Type Approval testing presently defines three cycles as the requirement. The difference in exposure is apparently predicated on allowing for sterilization or decontamination at the parts, material and assembly levels during the fabrication processes.

In the factory through launch sequence for flight articles, one heat sterilization exposure (equivalent to terminal heat sterilization) is applied as part of the flight acceptance testing. Since Type Approval employs three cycles, exceeding this number on the flight article would be presumed detrimental to the hardware and therefore, unacceptable. On this basis, up to two additional cycles can be used after flight acceptance exposure. One cycle is used in the terminal heat sterilization; the other is therefore available for recycle.

If we allow for one heat exposure of the parts, materials or assemblies (i.e., used either on receipt or during processing), the parts, materials, and assemblies have a latent capability for five additional treatments. On this basis, the subsystem/system can be exposed up to five cycles provided verification for interaction effects is accomplished as part of Type Approval testing.

In turn, this increase would permit two additional recycles at the Cape and help to alleviate the failure risk problem. This approach is shown concisely in Figure II A-1 below.

	Sterilization Cycles	
	Now	Alternate
Parts and Assemblies	6	6
Subsystem and System	3	5

Figure II A-1 Increase Qualification Requirements

Discussion and Analysis: From a program standpoint, this approach would entail increased cost to conduct the added subsystem/system Type Approval testing. No schedule impact is anticipated in the Type Approval testing for terminal heat sterilization as this testing is unlikely to overlap other requirements for the facility. Schedule impact will occur at the launch site, however, to allow for the additional cycles.

Under a Martin in-house study,[2] the parametric relationships shown in Figure II A-2 were derived. This graphic plot identifies the risk (expressed as probability of having a flight capsule available for launch) vs any estimated probability of surviving without failure the terminal heat sterilization and subsequent operations through launch. The individual curves reflect the decrease in risk with increasing recycle capability assuming

PROBABILITY OF ONE FLIGHT CAPSULE BEING READY AT LAUNCH FOR SUNDRY NOS. OF ALLOWABLE HEAT STERILIZATION CYCLES AND PROBABILITIES OF SURVIVING EACH STERILIZATION CYCLE. NO SPARING CONSIDERATIONS.

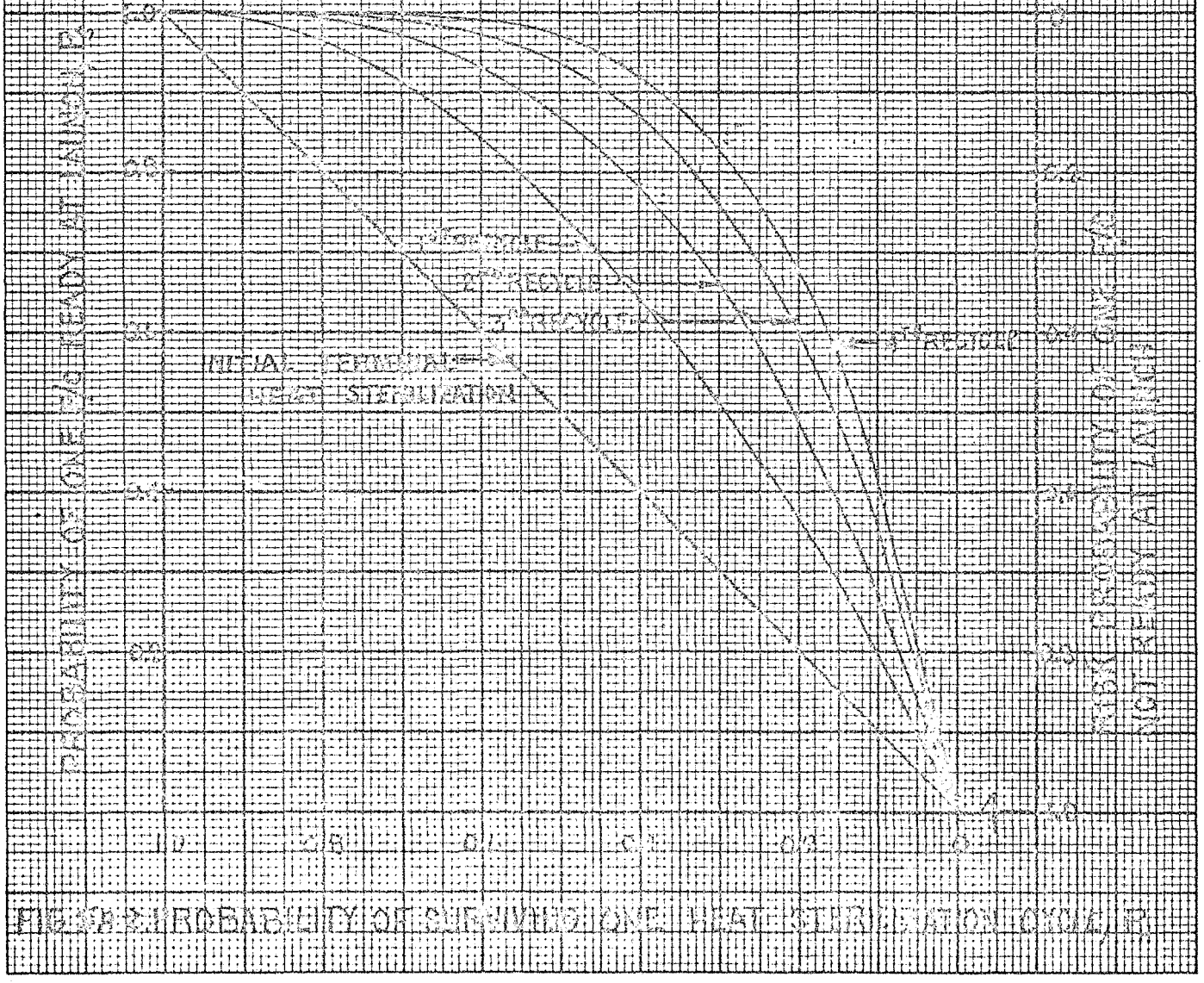

FIG. 2 PROBABILITY OF SURVIVING ONE HEAT STERILIZATION CYCLE

equal probability of failure for each cycle. (i.e., no reliability degradation effect). This analysis reveals the following improvement with increased recycle capability for assumed survival probabilities of .1 and .6.

Probability of Flight Worthy Unit After:	Estimated Probability of Surviving Heat Sterilization		Program Risk	
Initial Cycle	.1	.6	.9	.4
1st Recycle (Present Constraint)	.19	.84	.81	.16
2nd Recycle	.27	.93	.73	.07
3rd Recycle	.34	.97	.66	.03
4th Recycle (New Constraint)	.42	.99	.58	.01

Prior experience with launches of other missions at the Cape has shown a repetitive need for failure replacement during system checkout. These data imply a low probability of no failures in the period from completion of terminal sterilization through launch. On this basis the .1 summary above may be considered as representative of the potential improvement by added cycles.

Alternatively, one can assume a higher value, such as .6, as an outgrowth of the extensive R & D program on sterilizable parts, materials, components, processes, etc coupled with the developmental, type approval and flight acceptance testing under program aegis. With this assumption program risks are reduced to 1% provided launch site schedules permit this number of recycles.

Use of these additional recycle capabilities, however, can create other problems: (1) The additional exposures during Type Approval testing may result in failures that would not be experienced under the present three cycle requirement. Such failures could cause stretch out of the Type Approval testing to the point of affecting the flight articles. If successful, however, the added cycles afford higher reliability. (2) Additional cycles at the Cape will enhance slow reliability degradation processes affecting mission reliability after a protracted period of time.

Summary: This increased cycle capability approach will partially alleviate the failures after terminal sterilization problem provided: (1) survival probability can be increased to .6 or higher, and (2) launch site operations will allow for up to four (4) recycles. Principal weaknesses are:

a) No solution for heat sensitive items;

b) No positive assurance against failure to launch based on today's low probability of survival estimates;

c) Launch site schedule will be major constraint on its use.

B. Increased System Spares at Launch Site

Concept: As indicated previously present policy restricts terminal heat sterilization of the flight articles to the initial sterilization and one recycle. On this basis a unit cannot be

used for the mission if two successive failures are encountered. Additional system spares, therefore, warrants consideration as a means of assuring a flight article for launch.

Discussion and Analysis: Additional spares offers an advantage over higher repetitive cycles by contributing less reliability degradation. This gain is obtained by paying the high cost of additional system spares. Use of added spares is limited by processing capability at the launch site and the factory against specific program schedules.

A Martin Marietta study[3] established two spares for the projected Voyager program. Figure II B-1 shows a parametric plot of the spares aspect for a Voyager configuration of two flight capsules. Comparison of these probabilities with the recycle approach in Section II-A show equivalent improvement for two spares to that obtained for 6-cycle capability.* These curves can also be used in a reverse context. Thus, NASA can establish a desired program risk level such as .99. Spares requirements can be obtained from the curves for a given survival probability; or conversely, for an assigned spares level, the development and test programs can be sized to provide the requisite survival probability.

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* Joint use of these approaches would yield very low program risk--unfortunately, not practical because of excessive launch site schedule requirements.

PROBABILITY OF 2 F/C BEING READY AT LAUNCH VS. PROBABILITY OF A F/C SURVIVING ONE STERILIZATION CYCLE. EACH F/C CANNOT BE HEAT STERILIZED MORE THAN TWICE. PARAMETERS ARE 0, 1 & 2 SPARES.

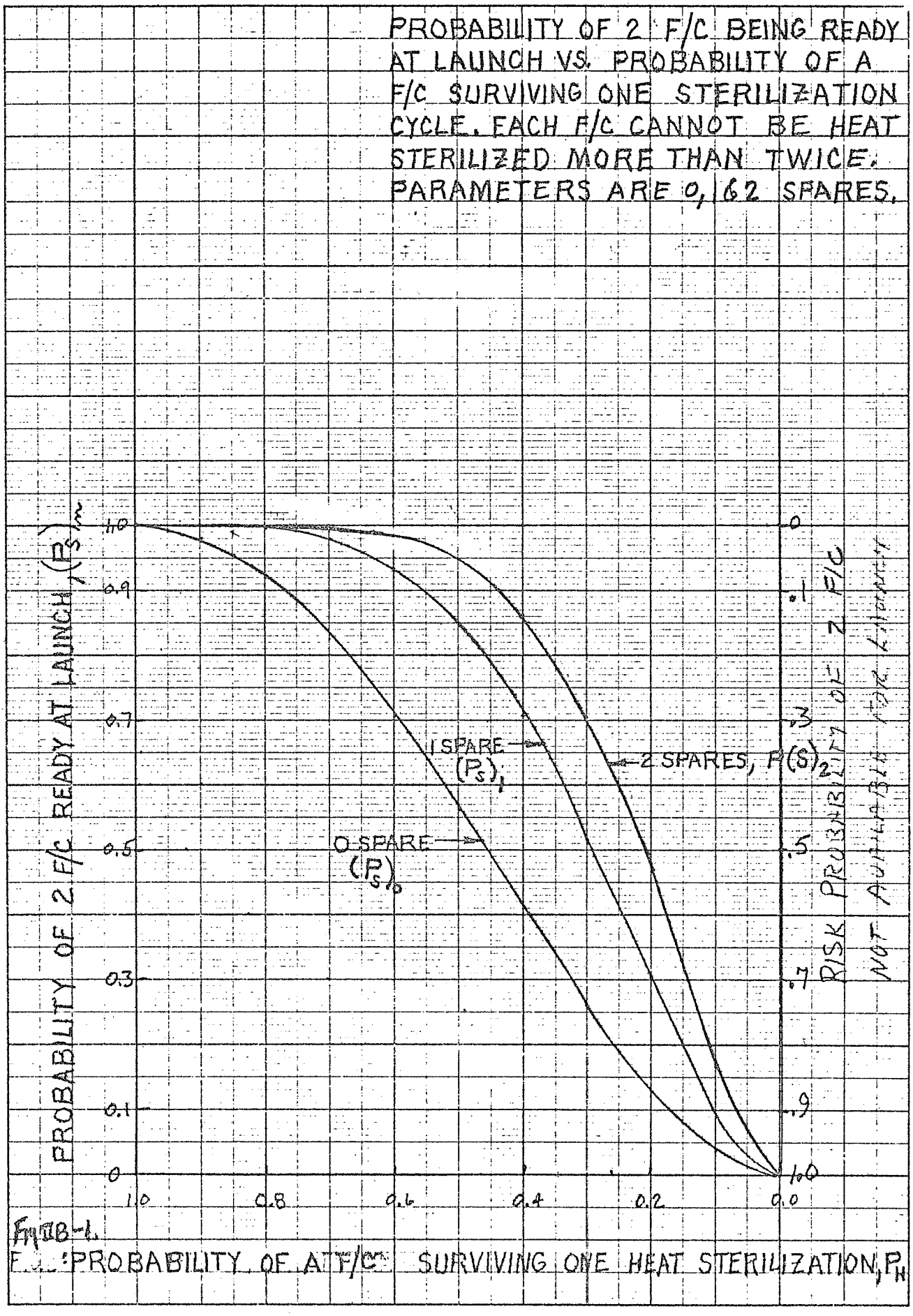

FIGURE B-1.

Summary: Increased system spares has only limited merit because:

1) No solution for heat sensitive items;

2) No positive assurance against failure to launch based on today's low probability of survival estimates;

3) Very costly approach if more than 2-3 spares are required;

4) Launch site schedule will be major constraint on its use.

III PRESENT POLICY WITH MODIFIED RECYCLE REQUIREMENTS

A. Recycle with Lowered Terminal Heat Sterilization Requirements

Concept: The terminal heat sterilization cycle is predicated on reduction of a total cumulative spore count on the spacecraft of 10^5. This maximum biota level of 10^5 spores just prior to the initial terminal heat sterilization applies to the accumulated contamination for the total assembly and test acceptance. On a comparable basis, a much lower spore count can be expected after repair of a sterilized spacecraft. Two conditions contribute to the lower count:

1) Replacement will be conducted in a Class 100 clean room;
2) The time for repair in which the canister is still open should be of the order of 1-2 days.

In turn, the lower contamination level warrants evaluating the merits of reducing the recycle heat sterilization to match the lower total spore count.

Discussion and Analysis: If we assume that the repair cycle yields a contamination level with a magnitude of 10^3, the terminal heat cycle can be decreased by 2-D values from the original treatment for 10^5 spores. Figure IIIA-1 shows the relationship between organisms killed and time of exposure at 125°C. With the estimated reduction of two orders of magnitude in the repair contamination level, seven less hours of sterilization at 125°C will be required. Considering the total terminal sterilization period including

heat up and cool down time, this gain is relatively small.

From a reliability standpoint, the major degradation effects on the hardware occur during the heat up period to the sterilization temperature. Continuation at this temperature adds to this initial degradation. Reduced time of exposure, therefore, does not materially affect the probability of detectable failures requiring replacement although it should yield improved mission reliability.

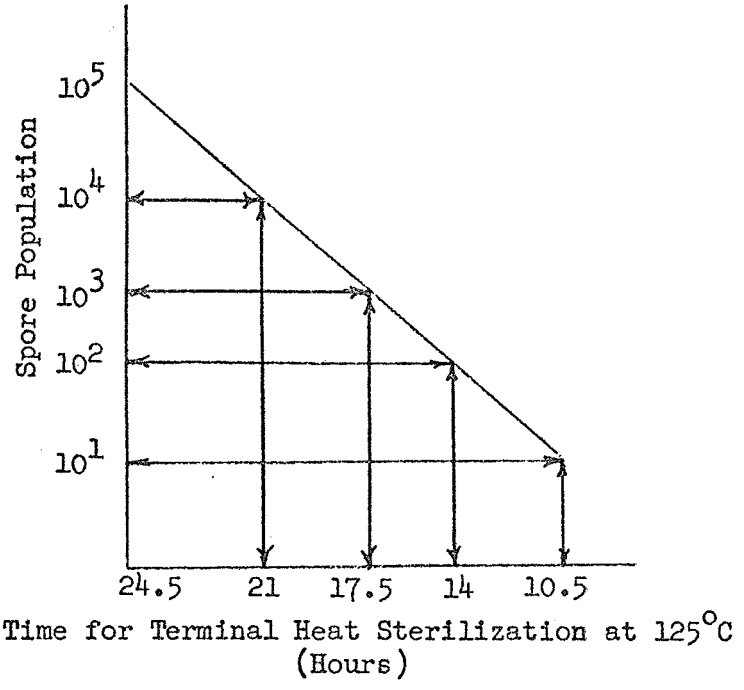

Figure IIIA-1 - Spore Kill vs Time at 125°C

Summary: This modification of present requirements has only marginal value. It provides no solution to the heat labile problem nor does it basically alleviate the failure cycle problem.

B. Recycle with Ethylene Oxide

Concept: After the terminal sterilization cycle, internal hardware is sterile. When the canister is opened to effect replacement, contamination will occur only on the surface of the hardware. If care is taken to prevent contamination of mating surfaces during the replacement operation, only surface contamination need be killed. Since ethylene oxide is used for surface treatment its application in the recycle phase warrants consideration.

Analysis and Discussion: Biological data show occasional "skips" with ETO. Accordingly, NASA has classified ETO as a decontaminant--not a sterilant. By NASA definition, a decontaminant reduces biological contamination but does not yield sterility. Since sterility with a 10^{-3} probability is the NASA requirement for the post terminal sterilization condition, ETO treatment cannot be used to meet this constraint.

Summary: This approach has merit but cannot be used with a "decontaminant". This concept warrants further study if R & D studies evolve a "surface sterilant" acceptable to NASA.*

* Martin Marietta was the successful contender to a recent JPL Request for Proposal to investigate the optimum conditions for ethylene oxide. Work under the ensuing contract may provide data to permit reclassification of a modified ETO treatment as a surface sterilant.

C. Recycle Using Sterile Repair/Sterile Insertion Concept

Concept: The primary problem source in the present requirements is the repetitive terminal heat sterilization constraints. If an aseptic repair/insertion technique were available, no repetitive operations would be needed. Replacement of failed items or insertion of heat sensitive items could then be accomplished after terminal sterilization.

Two basic approaches warrant evaluation. The first, termed "Assembly Sterilizer", is based on conducting these repair/insertion operations in a large sterile chamber. The second general concept is commonly called "sterile insertion". This approach is based on accomplishing aseptic replacements/insertions through access ports in the flight capsule.

A corollary facet of these concepts is the availability of sterile hardware for repair/insertion. This aspect must also be considered in evaluating each alternative.

Discussion and Analysis:

1) Assembly Sterilizer Concept: An artist's conception of the assembly sterilizer is shown in Figure III C-1. Based on initial exploratory work by General Electric[4], NASA Langley has recently issued an RFP won by Avco for a full scale design phase to be followed by fabrication of an experimental facility. The facility termed MAST for Model Assembly Sterilizer will be mobile so that it can be transported to the launch site if tests at

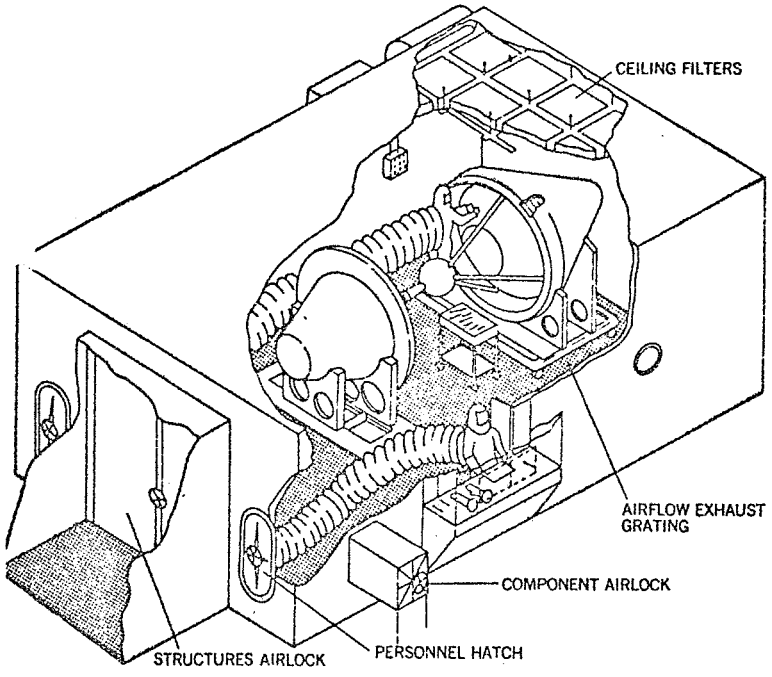

Figure III C-1 - Assembly Sterilizer

Langley verify its suitability for operational use. The concept as envisioned in its totality by J. Zanks of Langley is an excellent one. Final assembly through system test will be accomplished in a non-sterile but biologically controlled environment inside the MAST facility. The completed system-checked assembly in an open bio-canister condition will then be terminal heat sterilized by the MAST facility. This operation will sterilize both the vehicle and the interior of the MAST. Sterile entry of operators in suits* will be accomplished followed by system check. This arrangement provides for a much more detailed system checkout than is obtainable through the umbilical in the conventional approach. Replacement of failed hardware and insertion of heat labile items can be accomplished in this operation followed by aseptic sealing of the sterilization canister. The encapsulated spacecraft will then be removed for subsequent mating operations, etc.

If failure occurs downstream, the spacecraft will be returned to the MAST facility. The failed vehicle will enter a sterile MAST chamber through a lock after a sterilizing treatment to cleanse the contaminated external surface.**

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* Original concept as shown in Figure III C-1 used tunnel suits. Langley sponsored development of a separate suit permits greater operator freedom and flexibility of operation.

** The "return sequence" constitutes a potential bottleneck in actual practice because of assembly of other (spare) units in the MAST facility. From a cost standpoint, it is not desirable to build two or three MAST facilities (whether joined or separate) to eliminate this bottleneck. Other alternatives do not solve the problem. (Examples: Assemble all spares sterily to reduce time delay of making MAST sterile for the repair operation; eliminate all spares, etc.) As shown later, sterile insertion offers quick time response but suffers from lack of total accessibility. These diverse approaches complement each other and, in combination, offer a sound solution to all problems.

Using the man-in-suit operations the canister and heat shield will be removed, the failed part replaced, system test repeated and reassembly made into the sealed canister condition. No repetition of the terminal cycle is needed because the operations will be performed under aseptic conditions.

2) Sterile Insertion Concept: Sterile insertion is in an earlier stage of development than the assembly sterilizer. The concept is shown in Figure III C-2. The sterilization canister contains an access port covered by a plastic film barrier(1). After terminal sterilization the inside of the canister and the film are sterile and the external surfaces are contaminated from the launch site environment. Insertion is accomplished with a service bag which in its simplest form is a glove bag. The service bag is internally sterile and contains the necessary sterile hardware, a replacement barrier, and required tools for insertion. As shown in(2), the bag is heat sealed to the spacecraft barrier. External surface contamination on the barrier and service bag is enclosed within a lens shaped plastic pouch. A cut around the pouch along the center line of the heat sealed seam permits removal of the pouch and provides access to the interior of the spacecraft(3). Sterile repairs and installations can then be accomplished. The replacement barrier is then installed across the opening and heat sealed in place(4). Removal of the service bag is accomplished by cutting along the center line of the second seam(5).

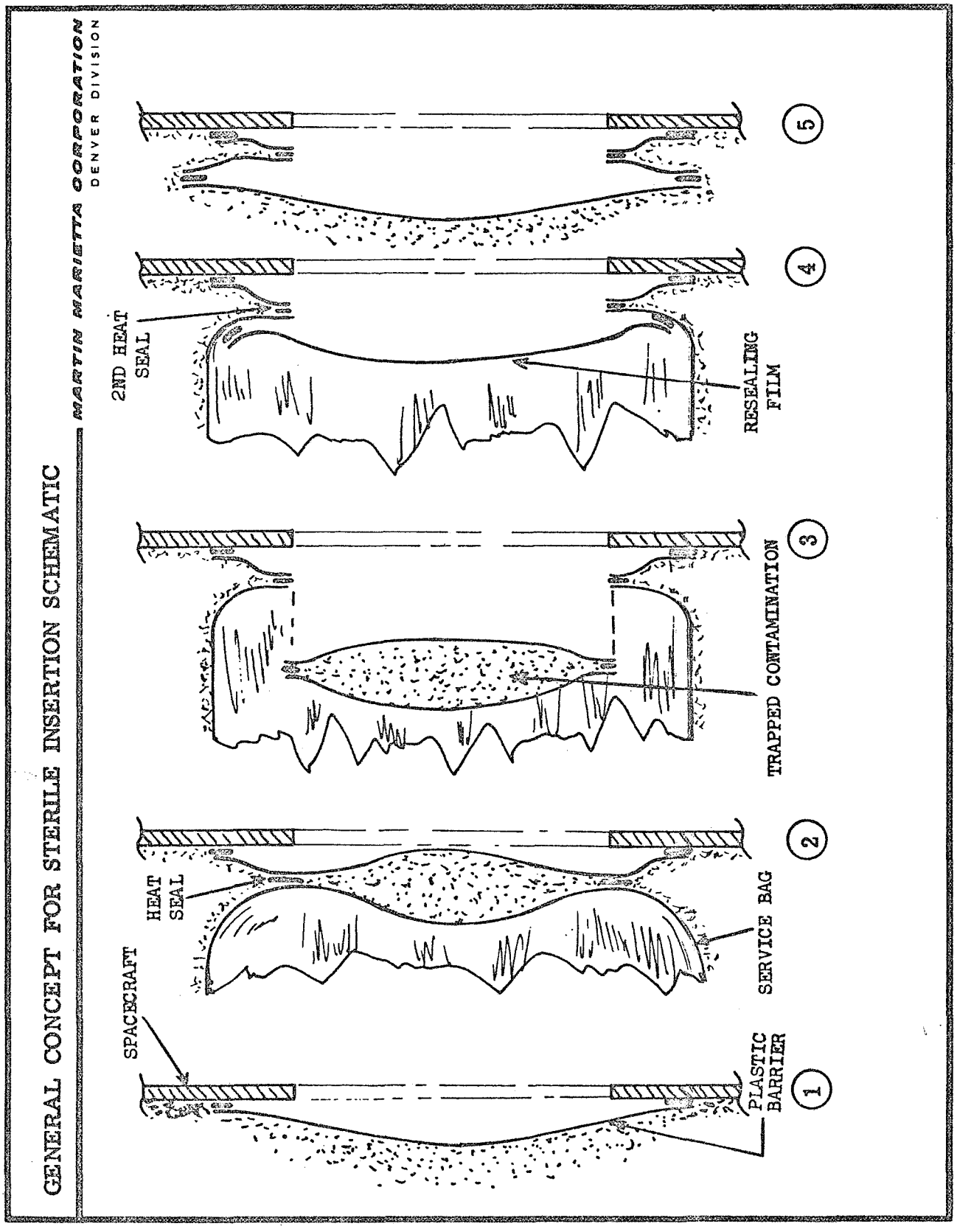

FIGURE III C-2

Under contract to NASA Headquarters[5], Martin Marietta has evolved a number of practical design concepts using this heat sealing concept. As shown in Figure III C-3 and III C-4, the heat sealing tool and cutting tool are self propelled. This feature minimizes the introduction of operator error in the sealing and cutting operations. Figure III C-5 shows the corresponding port opening design. Redundancy in the exterior and interior covers encasing the plastic barrier assures high reliability against violation of biological security.

Investigations by NASA Goddard and the Martin Marietta Corp. under a Marshall Space Flight Center contract[6] are establishing the biological characteristics and acceptability of the heat sealing and cutting operations.

From the foregoing description, the advantages and disadvantages of MAST and sterile insertion are identified in Figure III C-6. The principal weakness of MAST is the time required for the recycle step; This is the primary strength of sterile insertion. Conversely, lack of total accessibility is the predominant sterile insertion weakness but an obvious strength of MAST. In combination, total solution is achieved.

3) Sterile Components Aspect: MAST and sterile insertion require the availability of sterile spares and sterile heat sensitive hardware. Since the need to survive terminal heat sterilization is eliminated with these techniques, the method of

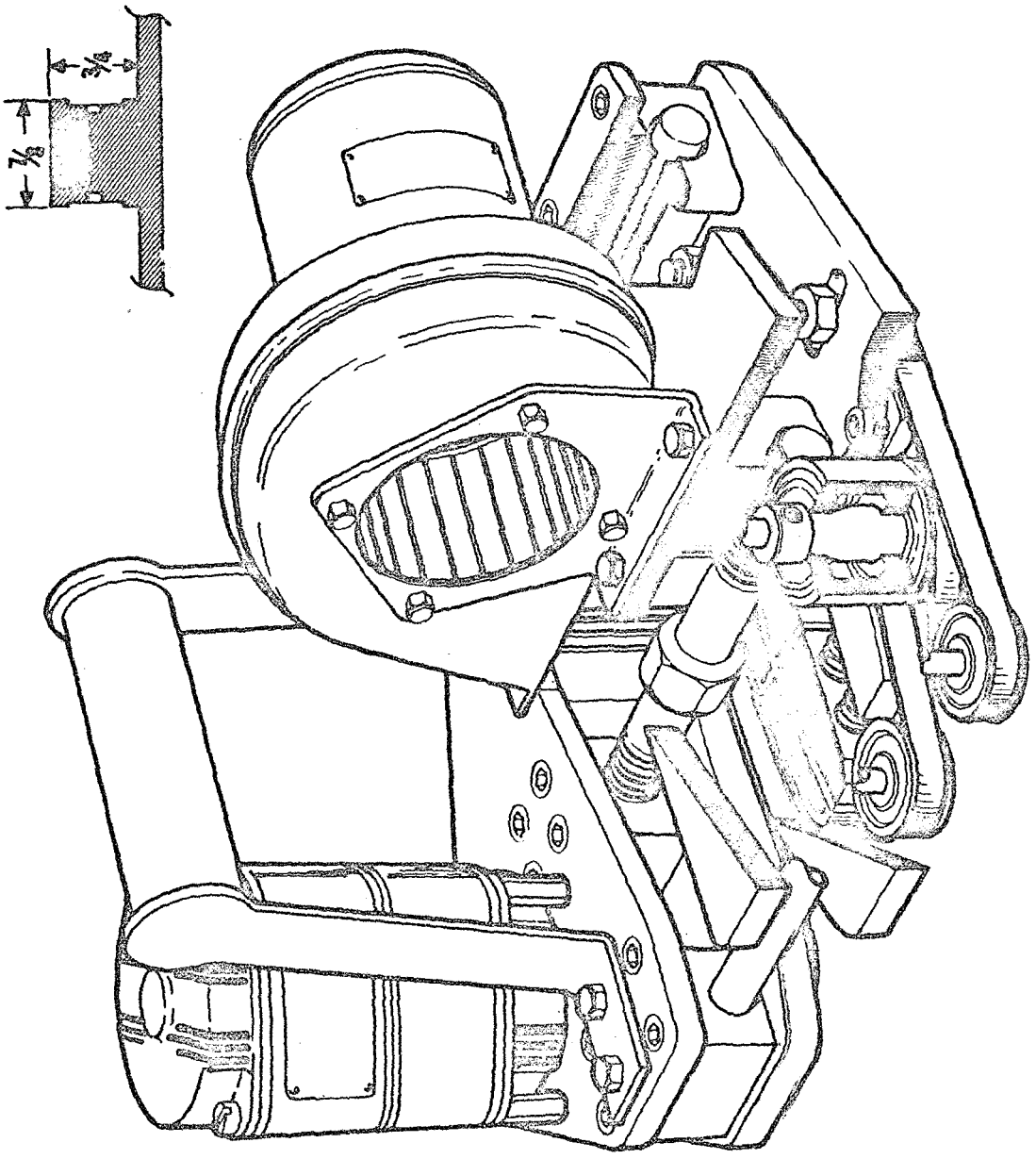

Figure III C-3 - Heat Sealing Tool

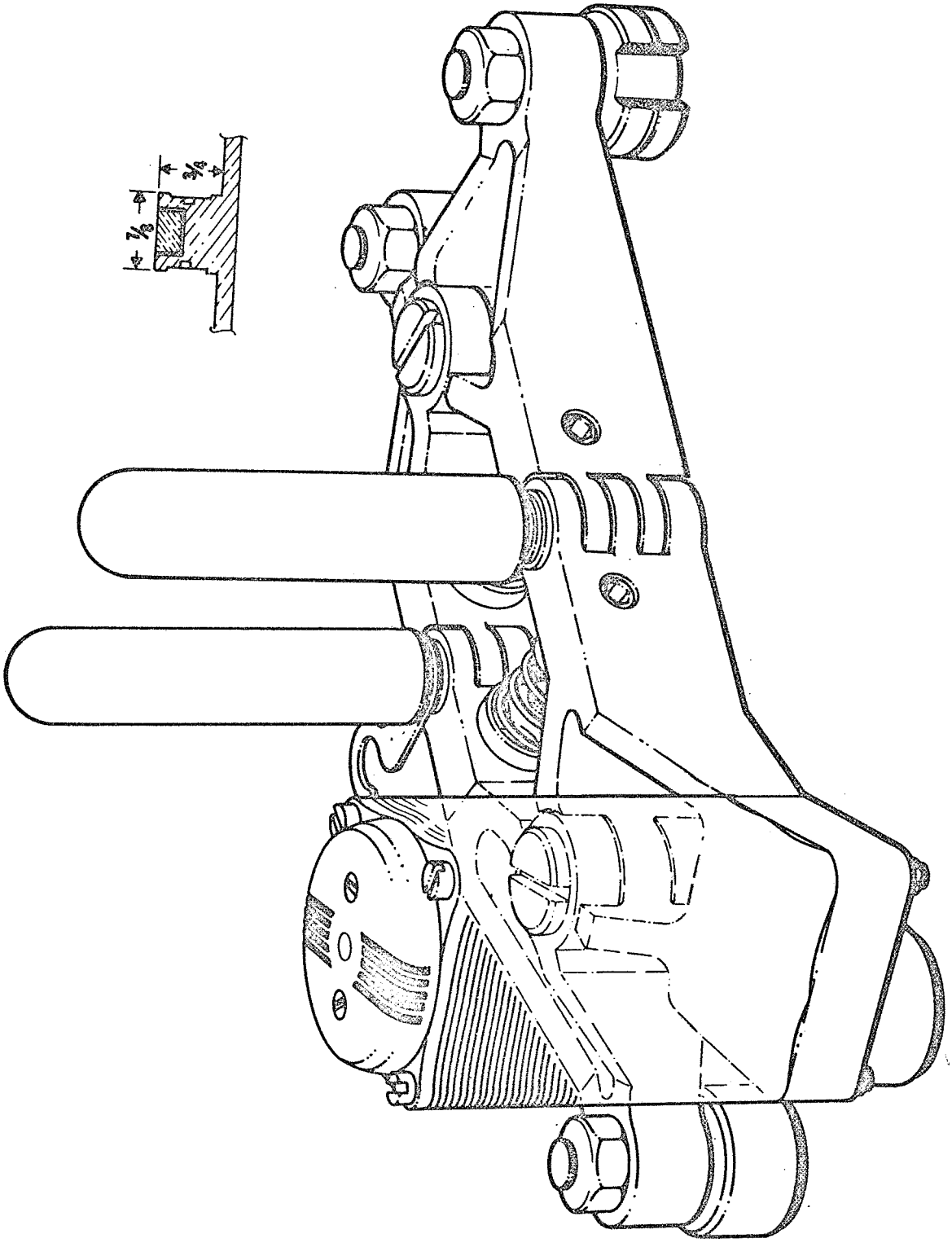

Figure III C-4 - Self-Propelled Cutting Tool

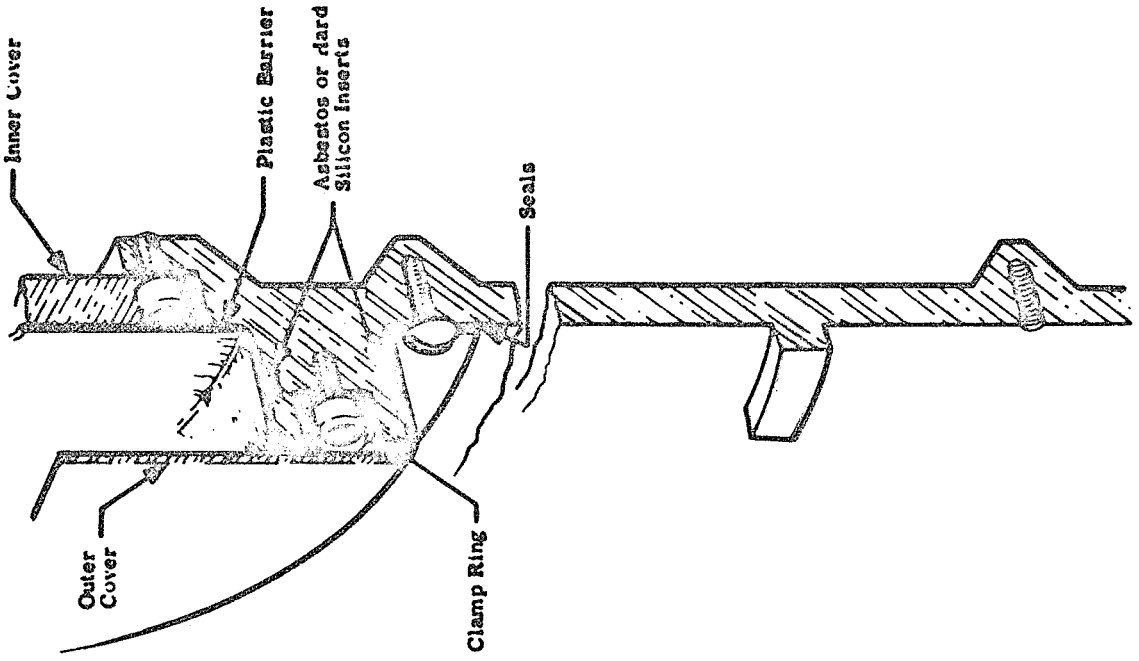

Figure III C-5 - Entry Port

MAST

ADVANTAGES

Complete accessibility for repair

Optimum use of standard spacecraft operations (except for short aseptic interval when man must be suited)

System test is improved

No requirement for interval heaters to achieve terminal heat sterilization

Shorter time to recycle than present methods but still days.

DISADVANTAGES

Time Limitations:

Requires return to MAST facility to conduct operations

Requires sterilization of exterior canister surface prior to entry into MAST for repair.

Longer time for operations by man in suit.

Bottleneck of other operations in progress inside MAST

Very high facility costs

NOT Proven yet

STERILE INSERTION

ADVANTAGES

Very short recycle time because no special site or sterilization operation is required.

Will be needed to introduce sterile heat labile items into MAST

Small cost for sterile insertion equipment.

NO special location needed to accomplish insertion operation.

DISADVANTAGES

Inaccesibility of some hardware will require other methods for repair of these items.

Small weight penalty for access ports on spacecraft

NOT Proven yet.

Figure III C-6 - Comparison of MAST and Sterile Insertion

sterilizing heat labile items can be selected to assure both sterility and failure free operation.

A major problem, however, exists in packaging of the spares and insertion hardware. Special packaging will be required to guard against biological contamination during transportation and handling. Of more import, however, are the requirements for all flyable hardware to meet the Flight Acceptance environments. New packaging concepts will be needed which permit reasonable duplication of the flight environment under packaged conditions without violation of the biological security of the hardware during the testing sequence. In addition, methods must be evolved to detect breaches of biological security.

McDonnell Douglas[7] is investigating sterile assembly with a challenge system to detect breaches of biological security. Under Langley contract[8] Martin Marietta is developing design concepts to solve the packaging problem for sterile assembled batteries.

Summary: These approaches have high merit to solve the total problem posed by terminal heat sterilization. Prior to their use, however, four major problems must be solved:

a) Prove that the technique meets the NASA contamination requirements;

b) Develop alternate sterilization techniques or sterile assembly procedures for each heat sensitive item;

c) Design and demonstrate special packaging for flight acceptance testing and for shipment of sterile hardware;

d) Evolve contamination detection techniques.

IV REDUCE IMPACT OF TERMINAL HEAT STERILIZATION AT LAUNCH SITE

A. Conduct Terminal Heat Sterilization at the Factory

Concept: A major risk in the present approach lies in the schedule impact of terminal sterilization on the relatively short time for pre-launch operations at the launch site. This alternate considers the possibility of reducing this effect by conducting the terminal heat sterilization at the factory.

Discussion and Analysis: At first glance this alternate appears to have a great deal of merit. It was, therefore, included in an evaluation conducted by the Martin Marietta Corporation in support of the Voyager program.[9] This study identified a number of cogent factors precluding this alternative. Key considerations included:

a) Failures in subsequent operations at the launch site would require either return to the factory or accomplishment of terminal heat sterilization on a recycle basis at the launch site. Return to the factory introduces logistics problems as well as lost time against the tight schedule. Recycling at the Cape constitutes a return to the same basic problems that this approach is attempting to avoid.

b) Under the present constraints, propellants are added just prior to the terminal sterilization operation because no insertions are permitted afterwards. These constraints

imply propellant loading at the factory and shipment in a fueled condition. Such shipments constitute a major safety consideration and would require special ICC approval. If sterile insertion of propellants after terminal sterilization were acceptable, this objection would disappear.*

Summary: This alternative does not appear to have merit because:

a) No gain in schedule time is really obtained.

b) It does not answer the heat sensitive hardware problem but compounds it by requiring sterile insertion of propellants, and

c) Special packaging will be required during transportation to guard against contamination enroute.

B. Decreased Temperature/Time Exposure

Concept: The likelihood of failure is related to the conditions of terminal heat sterilization. If these conditions can be reduced the failure probability will be reduced correspondingly. Two alternatives meet these conditions. These are:

a) Adjust the temperature/time exposure to the estimated

* This writer believes that sterile insertion of propellants warrants study. Its availability would yield appreciable weight savings in the vehicle. Concurrently it would eliminate a potentially serious explosive hazard during the terminal sterilization operation. Reference 10 has shown that propellants do not support bacterial life and therefore fosters the potential merits of this technique.

spore count prior to terminal sterilization, and

b) Use the integrated bio kill effect including the exposures above 105°C during heat up and cool down.

Discussion and Analysis:

Adjustment of the temperature/time exposure to the estimated spore count is an extension of the recycle with lowered terminal heat sterilization considered in Section III A. The only difference is the inclusion of the initial cycle in this approach. Without repeating the arguments, the same conclusion--only marginal value--is reached.

The second alternative has been recently adopted by NASA. A specific measure of the decrease in time/temperature during the terminal sterilization cannot be made because:

1) D values have not been established for temperatures other than 125°C, and

2) Experimental data is not available on the influence of specific configurations and heating arrangements on the heat up and cool down periods.

Analytical studies with simplified models show appreciably shorter dwell periods at 125°C. Although the time is decreased, the temperatures are essentially the same. Accordingly, the argument of Section III A is still pertinent.

Summary: Only marginal improvements are obtained with these alternatives; the basic problem of recycling effects and heat labile items is not solved.

C. Use Sterile Insulated Assemblies

The basic problems from terminal heat sterilization stem from the effect of the high temperature on the hardware. If high temperature exposures of these assemblies could be avoided in the terminal sterilization phase, the failure effect could be reduced or eliminated. Insulated biologically secure packages could meet these conditions if the internal assemblies were sterile. This sterility could be accomplished by sealing the packages at the end of the Flight Acceptance sterilization test.

Discussion and Analysis: Martin Marietta investigated this protective container concept. Thermal analyses were conducted for assumed conditions of terminal sterilization at 257°F (125°C) for 24 hours with a criteria that internal temperatures do not exceed 140°F (60°C). These analyses concluded:

"1) It is not feasible to design a container of the desired type using conventional solid insulations, i.e., insulations that do not require a high vacuum.

"2) Based on apparent thermal conductivity data available, it appears that super-insulation can provide a sufficiently low heat transfer rate that the desired container can be built; however, determination of unsteady state heat transfer rates with this type of insulation is not amenable to ordinary analytical techniques so that such determinations are approximations at best. In addition

fabrication of the container to eliminate heat "shorts", which would obviate the insulating effect of the super insulation itself, presents difficulties that appear to be insurmountable. The final answer can be obtained only by building and testing such a container.

"3) Designing a container which utilizes the heat-sink capabilities of a melting or boiling material, with or without a layer of silicone foam insulation, appears feasible."

From a program standpoint, this approach introduces a small delta during the assembly operations and the FA heat sterilization (sealing of box.) Concurrently, benefits are derived from reduction of the qualification requirements because the hardware will experience only one heat exposure and potentially no ethylene oxide exposure. Mission reliability will also be improved for the same reason.

Even if proven feasible from a thermal standpoint, this concept has two major disadvantages. These are: (1) A major weight penalty is added to accomplish the thermal insulation. (2) The insulation will retain internal heat as well as keeping external heat from affecting the equipment. The latter will cause high heat for operating hardware in the package. To overcome this failure condition, additional design complexity will be required to open or cool the insulated package using either mechanical or ordnance equipment. This added complexity may overbalance the

improved reliability from the protected condition during terminal heat sterilization.

Summary: Although the concept appears promising, its broad implementation for every hardware assembly would result in an untenable weight penalty coupled with added design complexity. If experimental work proves the approach is feasible, application to a limited number of problem hardware assemblies could be valuable.

V ELIMINATE TERMINAL HEAT STERILIZATION

A. Sterile Assembly

Concept: Terminal heat sterilization could be eliminated if the complete spacecraft were assembled sterily. This concept has really two categories:

a) Maintain aseptic conditions from inception of lowest assembly; and

b) Institute aseptic conditions during and after the Flight Acceptance heat sterilization.

Discussion: The technology for sterile assembly is reasonably well known from similar controlled operations in CW/BW warfare, pharmaceutical and chemical processing and gnotobiology. Detection of breaches in biological security can also be solved through application of the challenge system under development by McDonnell-Douglas Aircraft under contract to the Marshall Space Flight Center. Although the technology is available, this concept has many major disadvantages which would preclude its use for other than special heat sensitive items. In general, these disadvantages are:

1) Cost and time impact created by the nature of the isolator operation.

2) Major changes to, and limitations on, normal spacecraft assembly operations.

3) For category (a) (from inception) no heat exposure is used and internal biota contamination remains. This condition would be unacceptable under present requirements.

Conclusion: State of the art does permit application of this concept but it constitutes a too costly and time consuming solution for broad application to all hardware. Its use for heat sensitive items is warranted as an adjunct to MAST and sterile insertion.

B. Sterile Non-insulated Biologically Secure Assemblies

Concept: Enclose and seal the spacecraft assemblies/subsystems in sealed containers at the time of the FA heat sterilization treatment. Under these conditions the internally contained units will be sterile, internal biota will be killed, and only surface contamination (on the exterior of the sealed containers) remains to be sterilized in the terminal sterilization process. Use of a surface sterilization treatment would eliminate the terminal dry heat sterilization.

Discussion: Application of this concept requires an acceptable surface sterilant to be used during each mating operation (to prevent occluded biological contamination) and for the final terminal surface sterilization. Development of the containers poses no major engineering problems although their use will have a small impact on the assembly and testing operations.

Additional weight is introduced by the packaging. This small weight differential may be a reasonable penalty from the standpoint of the improved logistics and ease of "black box" replacement. Concurrently, the sealed packaging prevents exposure of the internal components to ethylene oxide. The concept was therefore used in the Martin Marietta Phase B study for packaging of the RCA tape recorder to eliminate the known ETO compatibility problem. Significant time and cost savings and higher reliability assurance are inherent in this concept by:

1. Qualification for ethylene oxide compatibility can be reduced considerably - Since the internal components will not be exposed to ETO, qualification to this environment can be eliminated. Accordingly, ETO qualification can be limited to the packaging materials and such exposed hardware as the liquid and solid engines, structure, etc.

2. A larger selection of space proven, heat compatible reliable hardware will become available for interplanetary mission application - At the present time, design selection is limited to relatively few items with proven history of space usage and substantiating data for compatibility with ETO and heat. The JPL extensive parts program has primarily established a list of heat sterilizable parts but data of ETO compatibility is not available for many of these items. Normal burn-in requirements for many electronic parts establish compatibility with the dry heat

sterilization environment but these parts cannot be used because of their unknown characteristics with ETO. If no ETO exposure were required, the selection spectra could be expanded to include burned-in, space proven parts from Air Force, NASA and other long lived earth orbit missions as well as JPL interplanetary programs.

If we consider this packaging concept under terminal heat sterilization conditions, a small improvement is obtained. Since the internal hardware is sterile, contamination is limited to the external surfaces of the boxes.* Dwell time during the terminal heat sterilization is therefore measured at the exterior surface of the box since it is the innermost contaminated point. This difference in measurement location will yield a slightly shorter terminal treatment. Note, however, that the box is not insulated. The internal parts are therefore heated and the probability of failure during terminal heat sterilization is not improved appreciably. Although these advantages are appreciable, this packaging concept does not eliminate the basic problems posed in this study. If a NASA approved surface sterilant were available, this approach would be very attractive.

Conclusion: This approach cannot be used to eliminate terminal heat sterilization until a surface sterilant is available.

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* Assumes sterilization of connectors between boxes during the assembly operation to eliminate entrapped (occluded) biota. This additional processing is deemed to add negligible cost and time to the total program dollars and schedule.

Nevertheless, it warrants serious consideration as a packaging approach for sterilizable interplanetary spacecraft because of the potential significant savings in cost and schedule coupled with higher reliability assurance and design flexibility.

C. Reevaluate Requirements

Approach: The sterilization requirement is based on a probability study of potential contamination of the plant. Reevaluation of these probability values to show that the basic COSPAR requirements can be met with a contaminated vehicle at launch would eliminate the need for terminal heat sterilization.

Discussion: An honest reappraisal is always valuable particularly where experimental data (e.g., probability estimates of biota survival under space flight conditions; survival and release probability estimates of internal biota contamination, etc) warrants such action. However, an analysis with a predetermined conclusion lacks integrity and will not stand up under scrutiny. We cannot condone evasion of the requirements by a numbers game.

Present NASA requirements for Mars are tentatively being applied to Venus. Considering the different conditions on these planets, a planetary quarantine analysis is warranted to establish a set of requirements for Venus.

Conclusion: This approach may eventually occur when experimental data is available for suitable probability estimates in

the planetary quarantine equations to show a contaminated spacecraft can be launched within the COSPAR constraints. At present, this depth of data is lacking and we must accept conservative rationale. A separate set of requirements is needed for Venus missions.

VI CONCLUSIONS AND RECOMMENDATIONS

A. Conclusions

Added resources with the present constraints fail to yield sufficient reduction in program risk to warrant the cost increment of additional spares or added qualification cycles. Cost and time constraints similarly rule out sterile assembly and sterilization at the factory site.

Only marginal improvements are obtained from shorter time exposures in the recycle through terminal sterilization. This fact negates the value of the alternatives of integrated cycles and decreased terminal sterilization during recycle. Insulated biologically secure assemblies are undesirable because of the associated penalties on payload weight, volume and mission reliability, non-insulated biologically secure assemblies do not alleviate the basic problems but are extremely attractive from other program considerations. This approach would warrant special attention if a surface sterilant were available.

Reevaluation of the planetary quarantine equation with a bias to eliminate the requirement is unacceptable under any circumstances. An objective study coupled with a reasonable rationale and experimental data is needed to establish requirements for Venus.

Significant merits are available from the combination of MAST and sterile insertion. These complementary approaches can

provide the needed reduction in program risk if acceptable biological security can be demonstrated.

B. Recommendations

1. Martin Marietta should encourage continued NASA sponsorship of programs on MAST and sterile insertion so that these needed techniques will be available for interplanetary unmanned missions.

2. Investigations should be instituted to develop a surface sterilant acceptable to NASA. These efforts should inclue experiments to establish conditions for ETO application which will permit its reclassification from a decontaminant to a surface sterilant.*

3. A study should be undertaken on the non-insulated packaging concept. This study should develop more detailed cost, time, reliability, design flexibility evaluations than the cursory coverage in this report. If the study confirms the preliminary thoughts in this report, NASA should eliminate the requirement for ETO qualification on non-exposed parts, materials and components.

* This writer feels that ETO is not needed for interplanetary programs in its present classification as a decontaminant. Short heat exposure will accomplish the same effect. If it cannot be reclassified as a surface sterilant, I would favor its deletion.

4. Continuing objective reevaluations of the planetary quarantine equation should be conducted to update NASA requirements as additional data becomes available. These analyses should treat Venus and Mars separately. Experimental investigations of specific probability terms is warranted to provide the data to substantiate or change the rationale used in establishing the NASA requirements.

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